In The United States Court of Federal Claims

No. 05-605V

(Filed Under Seal: March 2, 2010)

Reissued: March 19, 2010[1]

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PAMELA DOYLE, on behalf of KATELYN DOYLE,	*	
Petitioner,	*	Vaccine compensation case; Motion for review of final compensation decision; Causation – burden of proof – proximate temporal relationship; Use of credibility findings – *Moberly*.
v.	*	
SECRETARY OF HEALTH AND HUMAN SERVICES,	*	
Respondent.	*	

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OPINION

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Peter Harwood Meyers, National Law Center, Washington, D.C., for petitioner, with whom were student attorneys *David Faranda* and *Tian Tian Hu* (both of whom argued).

Alexis B. Babcock, Vaccine/Tort Branch, Civil Division, United States Department of Justice, Washington, D.C., with whom was Assistant Attorney General *Tony West*, for respondent.

ALLEGRA, Judge:

Petitioner, Pamela Doyle, on behalf of her minor daughter, Katelyn, seeks review of a decision issued by Chief Special Master Gary J. Golkiewicz on August 28, 2009, denying her petition for vaccine injury compensation. Petitioner brought this action pursuant to the National Vaccine Injury Compensation Program, 42 U.S.C. §§ 300aa-10 to 300aa-39 (2006), alleging that Katelyn suffered from idiopathic thrombocytopenic purpura (ITP) – a bleeding disorder in which the body's immune system attacks its own platelets – as a result of the measles-mumps-rubella (MMR) vaccination she received. On review, the Chief Special Master denied compensation,

[1] An unredacted version of this opinion was issued under seal on March 2, 2010. The parties were given an opportunity to propose redactions, but no such proposals were made. Nonetheless, the court has incorporated some minor changes into this opinion.

finding that Katelyn's ITP was not caused by the MMR vaccination. For the reasons that follow, this court affirms that decision.

I. BACKGROUND

A brief recitation of the facts provides necessary context.

Katelyn was born on October 10, 2001, following an uneventful pregnancy. On October 15, 2002, she was seen at Wake County Human Services (WCHS) and received the MMR and varicella vaccinations. On a subsequent visit to WCHS on April 15, 2003, Katelyn was seen by nurse Donna Jackson, who, after carefully examining her, found no abnormalities. The latter finding was consistent with a medical questionnaire filled out by Katelyn's mother during that visit, which listed no recent problems or other concerns.

When Katelyn again visited WCHS on July 8, 2003, her mother pointed out the presence of "multiple small redish [sic] purple bruises in various stages of healing on [Katelyn's] arms, legs and trunk." The same medical records from which this quote is taken reflect that while Katelyn "has always bruised easily . . . ever since [she] started walking," her mother was "more concerned now" based on a "purplish 'knot' in [the] center [of her side]." Blood work done on Katelyn on July 9, 2003, revealed a platelet count of only 19,000.[2] She was admitted to the Children's Hospital at the University of North Carolina at Chapel Hill with a chief complaint of thrombocytopenia.[3] There, she was diagnosed with ITP, based on what the treating physician characterized in his discharge summary as a "new-found thrombocytopenia and increased bruising." The same physician reported that Katelyn "has always had periodic bruises [that] do not go away quickly," adding that "[e]ven if they hold her tightly, she would get a bruise." He noted further, however, that there had been "[increased] severity of bruising over the last several months." Katelyn received treatment for ITP over the next year and, because her condition persisted, eventually was diagnosed with chronic ITP at her July 7, 2004, office visit. Currently, Katelyn's ITP is in remission.

On June 7, 2005, petitioner filed a petition for compensation under the Vaccine Act. On April 28, 2006, the Chief Special Master held a factual hearing. On December 22, 2006, the Chief Special Master found that there was no "persuasive information in this record to distinguish the bruising before and after the vaccination given on October 15, 2002" and that the bruising

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[2] A normal pediatric platelet level is over 150,000/mm. Under the Vaccine Act's Qualifications and Aids to Interpretation (QAI), which provide explanations and definitions for terms used in the Vaccine Injury Table (*see Terran ex rel. Terran v. Sec'y of Health and Human Servs.*, 195 F.3d 1302, 1307 (Fed. Cir. 1999), *cert. denied*, 531 U.S. 812 (2000)), thrombocytopenic purpura is defined by a "serum platelet count less than 50,000/mm<3>." 42 C.F.R. § 100.3(b)(8).

[3] Thrombocytopenia means "decrease in number of platelets, such as in thrombocytopenic purpura . . . ." Dorland's Illustrated Medical Dictionary 1906 (30th ed. 2003).

indicative of the onset of the ITP did not arise "until sometime after the April 2003 visit [to WCHS] and prior to the July visit." On September 27, 2007, and December 28, 2007, petitioner and respondent filed, respectively, their expert reports – the first by Dr. S. Gerald Sandler, the latter by Dr. James Nachman.[4]

An expert hearing was conducted on June 30, 2008. Both of the aforementioned doctors acknowledged then that the accepted temporal relationship between administering the MMR vaccine and the onset of ITP, as supported by the medical literature, is six weeks. Nonetheless, Dr. Sandler was convinced that Katelyn suffered from a rare form of ITP, afflicting only a very small percentage of the already small subset of children who develop the chronic (rather than the acute) version of the disease. He testified that Katelyn's chronic case was among the narrow band to have an "insidious" onset, meaning that the condition lingered "below the surface" for a period of time and was not immediately associated with the purpura or petechia that constitute the tell-tale signs of the disease.[5] According to Dr. Sandler, diagnosis of chronic ITP that presents insidiously is often made when a low platelet count is linked with earlier signs of the disease (such as bruising or bleeding) that did not raise concerns when first observed. As Dr. Sandler readily admitted, it is difficult to apply this sort of retrospective diagnosis to a two year-old child, let alone to pinpoint the onset date of this insidious form of ITP. Dr. Sandler, nonetheless, reckoned that Katelyn suffered this condition as the result of her MMR vaccination because: (i) there was no evidence of thrombocytopenia prior to her receipt of the vaccination; (ii) Katelyn's mother did not have ITP and thus had not transferred the antibodies to her child; and (iii) Katelyn had developed a chronic form of ITP less than 38 weeks after her vaccination.

Dr. Nachman disagreed. He testified that, despite her prolonged symptoms, Katelyn had a form of ITP that was more acute than chronic, and which arose six to nine months following her immunization. Dr. Nachman stated that he was unaware of any medical literature linking the MMR vaccine to ITP with an onset of 26-38 weeks post-vaccination. Without that nexus or any other explanation for the delay in her symptoms, Dr. Nachman did not believe that Katelyn's ITP was caused, in fact, by her MMR vaccination.

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[4] Dr. Sandler is a Professor of Medicine and Pathology at Georgetown University Medical Center and Director of Transfusion Medicine at Georgetown. He is a member of the Division of Hematology and Oncology at the Lombardi Cancer Center. He has published and lectured frequently regarding ITP. Dr. Sandler's clinical practice is not extensive and primarily involves adults. Dr. Nachman is a pediatric hematologist/oncologist, who is currently a Professor of Pediatrics at the medical school at the University of Chicago. His practice involves seeing 200-250 children and young adults in any given month.

[5] Only about five to ten percent of children suffer from the chronic version of ATP, with the remainder developing the acute version of the disease. Of the chronic sufferers, Dr. Sandler estimated that about five percent suffered what he termed the "insidious" version of ITP. Multiplying these percentages, one finds that Dr. Sandler was asserting that only between 0.25 and 0.5 percent of children with ITP developed the chronic/insidious version.

On August 28, 2009, the Chief Special Master denied petitioner's claim, finding that she had failed to establish that her ITP was caused-in-fact by the MMR vaccination. Characterizing the case as "a classic battle of the experts," the Chief Special Master found that "Dr. Nachman was more persuasive." Commenting further, he stated that "Dr. Nachman's testimony cogently explained why Katelyn's case was not 'atypical' and thus the onset of Katelyn's ITP was far removed from the medically acceptable time frame for onset." "Dr. Nachman provided a detailed explanation of the biological mechanism of ITP," the Chief Special Master further found, as deriving from an autoimmune response. He noted that Dr. Nachman believed that Katelyn's case was no different from many he had seen in his referral practice.[6] Relying on this testimony, the Chief Special Master determined that Katelyn's case of ITP had arisen too late to be attributable to her MMR vaccination.

By comparison, the Chief Special Master found that Dr. Sandler's testimony "was unpersuasive and failed the test of reliability," chastising it as "at times extremely confusing, internally consistent, and . . . result-oriented." The Chief Special Master then proceeded to analyze, at great length, Dr. Sandler's theory of causation.

First, he found that Dr. Sandler had failed adequately to support his view that there was a form of chronic ITP which arose insidiously in children. On this count, the Chief Special Master wrote –

> The key to his theory was that the five to ten percent of children that have the chronic form of ITP will present with a different clinical picture, that is with an insidious onset . . . . What was never established was the equating of chronic with insidious onset . . . . Dr. Sandler never made the case, despite several rounds of questioning by the undersigned, that chronic ITP presents in all instances insidiously. This is critical because without the insidious onset petitioners have no explanation for the lack of bruising, the extended time frame following immunization and the lack of support in the medical records.

The Chief Special Master observed, moreover, that none of the medical literature offered by petitioner supported Dr. Sandler's theory.

Second, the Chief Special Master expressed concern with Dr. Sandler's apparent inability to explain the etiology of this form of insidious/chronic ITP. He noted that both doctors were readily able to explain how acute cases of ITP arise in children, as involving an immune response

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[6] Comparing the two experts, the Chief Special Master wrote "[i]t is important to note that Dr. Sandler does not have an 'extensive' clinical practice presently and what practice he does have is primarily with adults," adding that, unlike Dr. Nachman, "[h]e is also not a pediatric hematologist and obviously not board certified as such." In this regard, he further noted that Dr. Nachman sees about ten new cases of ITP per year and has seen between 300 to 400 such pediatric cases over his career.

to antibodies produced in response to a virus. These antibodies mistake something on the surface of the platelets as the virus and, upon attaching to the platelets cause the spleen to remove them from the system. At some point this process peaks, creating, correspondingly, the crash in platelet count (and associated problems with bleeding and bruising) that characterize the acute onset of ITP. The Chief Special Master rejected Dr. Sandler's attempt to analogize the insidious form of ITP to the HIV virus, agreeing with Dr. Nachman that the analogy was inapt and thus unhelpful.[7] In the view of the Chief Special Master, this left Dr. Sandler and, in turn, petitioner with no real explanation as to how the chronic form of the ITP virus arises insidiously.

Finally, the Chief Special Master opined that Dr. Sandler's model of insidious presentation did not track the observations made in Katelyn's medical records. The latter records, he found, contained no earlier evidence of bruising or bleeding that would constitute symptoms of chronic ITP when viewed retrospectively – "the medical records do not record any signs of bleeding subsequent to immunization until nine months after." Critically, he indicated that Dr. Sandler had essentially admitted that if there was an insidious onset – that Katelyn's ITP was percolating below the surface without evidence of bruising – he could not say whether the ITP began prior to the immunization.

To summarize, the Chief Special Master ruled that Dr. Sandler's testimony was unreliable because it amounted "to one assumption built upon another." The Chief Special Master stated that Dr. Sandler –

> assumes that Katelyn has a chronic form of ITP that presents insidiously. We know from Dr. Nachman and the petitioner's literature that not all chronic ITP presents insidiously. Dr. Sandler assumes that Katelyn's ITP began post-immunization despite his concession that we have no reliable historical data to rely on. He assumes that the mother failed to spot [indicators of ITP] prior to the gross bruises. He maintains that this is a chronic ITP presenting insidiously despite the absence of any evidence of minor bruising prior to the diagnosis of ITP despite the literature and Dr. Sandler's testimony regarding his adult model stating that indicators of ITP will manifest prior to the obvious signs. Then finally, Dr. Sandler assumes a

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[7] In analogizing the "insidious character" of some chronic ITP to the HIV model of infection, Dr. Sandler focused on the potential for a delayed immune-response to allow years to pass before full-blown AIDS develops, and also on the fact that HIV is capable of causing acute immune ITP secondary to the infection. The Chief Special Master and Dr. Nachman rejected this analogy, based on the fact that, as Dr. Nachman testified, the MMR vaccine is "a live, attenuated virus which doesn't seem to persist," whereas HIV is an active infection that kills immune cells and paralyzes the immune system. Dr. Nachman further opined that, while HIV can cause thrombocytopenia, it presents as an entirely different phenomenon due to HIV's effect on the immune system, and often goes away when HIV patients are treated with antiretroviral drugs. On this basis, the Chief Special Master adopted Dr. Nachman's conclusion that "[y]ou can't draw any analogy from HIV to ITP."

> temporal relationship between vaccine and injury of 38 weeks despite admittedly not knowing when the onset occurred.

On this basis, the Chief Special Master denied the petition, finding that there was no evidence to support a finding that Katelyn's ITP arose within the accepted post-vaccination time frame or that a proximate temporal relationship of the ITP to the MMR vaccination otherwise existed. The Chief Special Master, therefore, held that petitioner had failed to establish by a preponderance of the evidence that the MMR vaccination was the legal cause of Katelyn's ITP.

On September 27, 2009, petitioner filed a motion to review the Chief Special Master's decision. On October 27, 2009, respondent filed its response to this motion, to which petitioner replied on November 3, 2009. On January 28, 2010, the court conducted oral argument.

II. DISCUSSION

Under the Vaccine Act, this court may review a special master's decision upon the timely request of either party. *See* 42 U.S.C. § 300aa-12(e)(1)-(2). In that instance, the court may: "(A) uphold the findings of fact and conclusions of law . . . ; (B) set aside any findings of fact or conclusion of law . . . found to be arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law . . . , or; (C) remand the petition to the special master for further action in accordance with the court's direction." *Id*. at § 300aa-12(e)(2)(A)-(C). Findings of fact and discretionary rulings are reviewed under an "arbitrary and capricious" standard, while legal conclusions are reviewed *de novo*. *Munn v. Sec'y of Health and Human Servs.*, 970 F.2d 863, 870 n. 10 (Fed. Cir. 1992).[8]

Within this framework, petitioner insists that "the final decision was not made in accordance with law." Specifically, she asserts that the Chief Special Master "did not correctly follow the legal standards that have been enunciated by the United States Court of Appeals for the Federal Circuit in *Althen v. Sec'y of Health & Human Servs.*, 418 F.3d 1274 (Fed. Cir. 2005) and other recent Federal Circuit cases." She further argues that the Chief Special Master compounded his errors by impermissibly making and relying upon credibility findings regarding her expert. As will be seen, however, these arguments make far too much of too little.

As part of her burden of proof, the petitioner must establish that her injuries were caused by a vaccine listed on the Vaccine Injury Table. *See* 42 U.S.C. § 300aa-11(c)(1)(C). The petitioner may meet this burden by either demonstrating, by preponderant evidence, that her injury meets the criteria in the Table, or otherwise by proving causation-in-fact. The parties agree that the injury alleged here does not meet the criteria in the Table and that petitioner must instead endeavor to prove causation directly. *See de Bazan v. Sec'y of Health and Human Servs.*, 539

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[8] *See also Lampe v. Sec'y of Health and Human Servs.*, 219 F.3d 1357, 1360 (Fed. Cir. 2000); *Saunders v. Sec'y of Health and Human Servs*., 25 F.3d 1031, 1033 (Fed. Cir. 1994); *Savin ex rel. Savin v. Sec'y of Health and Human Servs*., 85 Fed. Cl. 313, 315 (2008).

F.3d 1347, 1351 (Fed. Cir. 2008); *Grant v. Sec'y of Health and Human Servs*., 956 F.2d 1144, 1147-48 (Fed. Cir. 1992). The Federal Circuit has held that "causation-in-fact in the Vaccine Act context is the same as 'legal cause' in the general torts context." *de Bazan*, 539 F.3d at 1351 (quoting *Shyface v. Sec'y of Health & Human Servs.*, 165 F.3d 1344, 1352 (Fed. Cir. 1999)); *see also Pafford v. Sec'y of Health and Human Servs*., 451 F.3d 1352, 1355 (Fed. Cir. 2006), *cert. denied*, 551 U.S. 1102 (2007). To satisfy this standard, a petitioner need not show that the vaccine was the sole or predominant cause of her injury, but only that it was a substantial factor. *Walther v. Sec'y of Health & Human Servs*., 485 F.3d 1146, 1150 (Fed. Cir. 2007) (citing *Shyface*, 165 F.3d at 1352).

In *Althen*, the Federal Circuit refined this proof standard, holding that to show causation-in-fact, a petitioner must establish by a preponderance of the evidence: "(1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury." *Althen*, 418 F.3d at 1278; *see also Capizzano v. Sec'y of Health and Human Servs.*, 440 F.3d 1317, 1324 (Fed. Cir. 2006). To meet this burden, a "petitioner must provide a reputable medical or scientific explanation that pertains specifically to the petitioner's case, although the explanation need only be 'legally probable, not medically or scientifically certain.'" *Moberly ex rel. Moberly v. Sec'y of Health and Human Servs.*, 592 F.3d 1315, 1322 (Fed. Cir. 2010) (quoting *Knudsen v. Sec'y of Health & Human Servs.,* 35 F.3d 543, 548-49 (Fed. Cir. 1994)).

There is no disagreement that petitioner met the first prong of the *Althen* test because, as the Table indicates, the MMR vaccine can cause ITP. And there is little discussion in either the opinion below or the parties' briefs regarding the second *Althen* prong. The parties' arguments, rather, center on whether the Chief Special Master correctly found that petitioner had not made an adequate showing of a proximate temporal relationship between the MMR vaccination and her particular case of ITP. To demonstrate a "proximate temporal relationship" in causation-in-fact cases, a petitioner must provide "preponderant proof that the onset of symptoms occurred within a time frame for which, given the medical understanding of the disorder's etiology, it is medically acceptable to infer causation-in-fact." *de Bazan*, 539 F.3d at 1352; *see also Althen*, 418 F.3d at 1281; *Rotoli v. Sec'y of Health and Human Servs.*, 89 Fed. Cl. 71, 79 (2009).

Contrary to petitioner's claims, the Chief Special Master correctly applied *Althen* and its progeny in this case. He did not impose a heightened burden of proof on petitioner, but merely required her to demonstrate a reasonable biological plausibility of a medically-appropriate temporal relationship. The decision, in fact, recites *haec verba* from many of the same opinions quoted above. Nor is this case like those in which a special master has been found to deviate from the accepted standards by demanding certain types of proof to establish causation (*e.g.*, epidemiologic studies, general acceptance of petitioner's theory in the scientific or medical communities). *Cf. Andreu v. Sec'y of Health & Human Servs*., 569 F.3d 1369, 1377-78 (Fed. Cir. 2009); *Capizzano*, 440 F.3d at 1325-26. To the contrary, this court perceives no significant difference between the standards outlined and applied in the decision below and those enunciated by the Federal Circuit in decisions like *Althen* and *Shyface*.

It would seem, then, that petitioner's quarrel must be with the Chief Special Master's application of the legal standard to the evidence at hand and, in particular, with his findings regarding Dr. Sandler's testimony. The Chief Special Master identified three major flaws in that testimony. First, he found that Dr. Sandler failed to explain the etiology of a form of ITP that would be both chronic and insidious. And, in fact, while he posited the existence of a rare and essentially undocumented form of ITP, Dr. Sandler did little to explain how that form of chronic ITP arises. *See Pafford*, 451 F.3d at 1358 (upholding the denial of compensation where experts did not provide sufficient evidence that a disease occurred within the medically acceptable time frame). Second, the Chief Special Master faulted Dr. Sandler for not explaining how his theory fit the progression of symptoms revealed by Katelyn's medical records. The doctor's failure is easy to understand for while those records suggest that Katelyn had "always" had bruising issues, they do not document any increased pattern of bruising proximate to when the MMR vaccine was administered – indeed, when Katelyn was examined by a nurse six months after the vaccination, no abnormalities were reported. *See Moberly*, 592 F.3d at 1325 (upholding the denial of compensation where there was no evidence linking the theory offered to the petitioner's recorded symptoms). Finally, the Chief Special Master found that Dr. Sandler was unable to establish, under his causation theory, whether the insidious onset of the chronic ITP began before or after the MMR vaccination. Dr. Sandler readily acknowledged this problem, although perhaps not understanding fully the crater it left in his causation theory. *See Ryman v. Sec'y of Health and Human Servs*., 65 Fed. Cl. 35, 41 (2005) (upholding the denial of compensation where an expert's testimony could not place onset after the vaccination).

Petitioner has not shown these findings to be erroneous. The practical upshot of the deficiencies in the record here – exacerbated, as they are, by the contrary testimony of Dr. Nachman – is to make arguments regarding the particular burden of proof employed by the Chief Special Master almost immaterial. Laid bare, petitioner's arguments reflect little more than mere disagreement with the finding that petitioner failed to establish a proximate temporal relationship between the vaccination and the onset of the ITP. "Such naked claims," this court has stated in analogous circumstances, "by all appearances unsupported by anything in the record, fall far short of meeting the heavy burden of demonstrating that these findings were the product of an irrational process and hence arbitrary and capricious." *JWK Int'l Corp. v. United States*, 52 Fed. Cl. 650, 660 (2002), *aff'd*, 56 Fed. Appx. 474 (Fed. Cir. 2003).

Nor did the Chief Special Master inappropriately use credibility findings. To be sure, the decisional law indicates that a special master may not "cloak the application of an erroneous legal standard in the guise of a credibility determination, and thereby shield it from appellate review." *Andreu*, 569 F.3d at 1379; *see also Therasense, Inc. v. Becton, Dickinson and Co.*, 2010 WL 254900, at *29 (Fed. Cir. Jan. 25, 2010). But, as the Federal Circuit recently emphasized, "[t]hat is not to say . . . that a special master, as the finder of fact in a Vaccine Act case, is prohibited from making credibility determinations regarding expert testimony." *Moberly*, 592 F.3d at 1325. Rather, in vaccine cases, like any other case involving an expert witness, "[a]ssessments as to the reliability of expert testimony often turn on credibility determinations, particularly . . . where there is little supporting evidence for the expert's opinion." *Id*. at 1325-26; *see also de Bazan*, 539 F.3d at 1353-54; *Pafford*, 451 F.3d at 1359. Contrary to petitioner's claim, special masters thus "are

entitled – indeed, expected – to make determinations as to the reliability of the evidence presented to them and, if appropriate, as to the credibility of the persons presenting that evidence." *Moberly*, 592 F.3d at 1326.[9]

In the case *sub judice*, the Chief Special Master did not camouflage his use of an unduly stringent legal test with credibility findings for at least one good reason: there was nothing to hide, as the proper standard was employed. Nor did the Chief Special Master create holes in petitioner's proof by disregarding portions of her expert's testimony – he merely highlighted the gaps that were already there. The credibility findings here thus served only to underscore the result the Chief Special Master reached when he carefully applied the correct legal standard to what, upon a lengthy analysis of the testimony, expert reports and medical records, proved unconvincing expert evidence. This case thus is not like *Andreu* – the situation here is altogether different. *See Broekelschen*, 89 Fed. Cl. at 346 ("The special master in this case did not use a credibility determination as a ruse to pick and choose the relevant evidence or to apply an incorrect legal standard. Instead, the special master cited the demeanor of the experts as one factor among many informing his decision."). As such, petitioner's claims on this count also fall well short of the mark.

III. CONCLUSION

No doubt Dr. Sandler is extraordinarily qualified to testify regarding ITP. But, proof of causation entails more than having a well-qualified expert proclaim that the vaccination caused a disease. Mere conclusory opinions – or ones that are nearly so as unaccompanied by elaboration of critical premises – will not suffice as proof of causation, no matter how vaunted or sincere the offeror. *See Moberly*, 592 F.3d at 1324 ("the special master is entitled to require some indicia of reliability to support the assertion of the expert witness"). Here, the deficiencies identified and well-documented by the Chief Special Master in his findings leap from the pages of the record – this court can no more ignore them than could the Chief Special Master. Despite the dedicated efforts of her student counsel, petitioner thus has not shown that the resulting decision is either legally or factually erroneous. As a result, the motion for review is hereby **DENIED**. No costs.

IT IS SO ORDERED.[10]

s/ Francis M. Allegra
Francis M. Allegra
Judge

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[9] *See also de Bazan*, 539 F.3d at 1354 (explicitly upholding the special master's determination that the testimony of an expert was more "credible and probative" than that of another expert); *Bradley v. Sec'y of Health and Human Servs*., 991 F.2d 1570, 1575 (Fed. Cir. 1993) (affording great deference to a special master's credibility findings); *Broekelschen v. Sec'y of Health and Human Servs*., 89 Fed. Cl. 336, 345-46 (2009).

[10] This order shall be unsealed, as issued, after March 16, 2010, unless the parties, pursuant to Vaccine Rule 18(b), identify protected and/or privileged materials subject to redaction prior to said date. Said materials shall be identified with specificity, both in terms of the language to be redacted and the reasons for that redaction.